The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

Paper No. 52

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte LUC MONTAGNIER, JEAN-CLAUDE CHERMANN,
FRANCOISE BARRE-SINOUSSI, FRANCOISE BRUN-VEZINET,
CHRISTINE ROUZIOUX, WILLY ROZENBAUM,
CHARLES DAUGUET, JACQUELINE GRUEST,
MARIE-THERESE NUGEYRE, FRANCOISE REY,
CLAUDINE AXLER-BLIN, SOLANGE CHAMARET,
ROBERT C. GALLO, MIKULAS POPOVIC, and
MANGALASSERIL G. SARNGADHARAN

Application No. 08/019,297

HEARD December 11, 2001

Before WINTERS, ADAMS, and GRIMES, <u>Administrative Patent Judges</u>.
GRIMES, <u>Administrative Patent Judge</u>.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 28-30, 35, 36, 42, and 45-48. Claims 43 and 44 have

Appeal No. 2000-1929 Application No. 08/019,297

been allowed. Claims 28 and 45 are representative of the claims on appeal and read as follows:

- 28. An purified immunological complex comprising a protein of human immunodeficiency virus type 1 (HIV-1) and an antibody against said protein, which antibody binds with said protein, wherein said protein is core protein of HIV-1.
- 45. An antibody directed against an antigen present in an extract of HIV-1 virus; wherein said antibody is formed using an HIV-1 extract or purified HIV-1 protein in animals; and wherein said antigen is selected from the group consisting of p25, p15, 36, p42, and p80.

The examiner relies on the following references:

Di Marzo Veronese et al. (Di Marzo Veronese), "Monoclonal antibodies specific for p24, the major core protein of human T-cell leukemia virus type III," <u>Proc. Natl. Acad. Sci. USA</u>, Vol. 82, pp. 5199-5202 (1985)

Seaver, "Monoclonal Antibodies in Industry: More Difficult Than Originally Thought," Genetic Engineering News, Vol. 14, No. 14, pp. 10, 21, (1994)

Claims 28-30, 35, and 42 stand rejected under 35 U.S.C. § 101 as lacking utility, and under 35 U.S.C. § 112, first paragraph, as being based on a specification that does not adequately teach how to use the claimed invention.

Claims 28-30, 35, 36, 42, and 45-48 stand rejected under 35 U.S.C.

§ 112, first paragraph, as being based on a specification that does not enable or adequately describe the claimed invention.

Claims 28-30, 35, 36, 42, and 45-48 stand rejected under 35 U.S.C.

§ 102(b) as anticipated by Di Marzo Veronese.

We reverse the written description rejection of claims 30 and 42 but affirm the remainder of the rejections.

Background

Appellants' specification discloses immunoassays for diagnosis of acquired immune deficiency syndrome (AIDS).¹ The present application claims the benefit of priority under 35 U.S.C. §§ 119 and 120 to applications dating back to 1983. The specification discloses the isolation of the AIDS virus, referred to in the specification as LAV₁. See, e.g., page 3, lines 27-28.

The specification also discloses some information about the viral proteins.

See pages 7-8:

In order to determine which viral antigen was recognized by antibodies present in the patient's sera, several immunoprecipitation experiments were carried out. Cord lymphocytes infected with virus from patient 1 and uninfected controls were labelled with [35]methionine for 20 hours. Cells were lysed with detergents. . . . Labelled virus released into the supernatant was banded in a sucrose gradient. Both materials were immunoprecipitated by antiserum to HTVL-1 [sic, HTLV-1] p24, by serum from patient 1, and by serum samples from healthy donors. Immunocomplexes were analyzed by polyacrylamide gel elctrophoresis [sic] under denaturing conditions. A p25 protein present in the virus-infected cells from patient 1 and in LC1 cells infected with this virus was specifically recognized by serum from patient 1.

The specification discloses that the viral p25 protein is likely to be located in the viral core.

The main protein (p25) detected after purification of ³⁵S-methionine-labelled virus has a molecular weight of about 25,000 (or 25K). This is the only protein recognized by the serum of patient 1. By analogy with other retroviruses, this major protein was considered to be located in the viral core.

3

¹ The specification also refers to AIDS as "lymphadenopathy syndrome," or "LAS."

Appeal No. 2000-1929 Application No. 08/019,297

Page 8, lines 10-15. The specification also provides the following description of the other proteins detected by denaturing polyacrylamide gel electrophoresis:

The viral origin of other proteins seen in polyacrylamide gel electrophoresis of purified virus is more difficult to assess. A p15 protein could be seen after silver staining, but was much weaker after ³⁵S-methionine perhaps due to the paucity of this amino-acid in the protein. In the higher MW range, a contamination of the virus by cellular proteins, either inside or outside the viral envelope, is likely. A 36K and a 42K protein and a 80K protein were constantly found to be associated with the purified virus and may represent the major envelope proteins.

Page 8, lines 21-31.

The specification teaches the use of extracts of viral proteins for diagnosing AIDS. "The invention further relates to a method of in vitro diagnosis of LAS or AIDS, which comprises contacting a serum or other biological medium from a patient to be diagnosed with a viral extract . . . and detecting the immunological reaction." Page 10, line 30 to page 11, line 2. The viral extracts useful in this assay are defined at page 9, lines 1-4: "The invention concerns more particularly the extracts of said virus as soon as they can be recognized immunologically by sera of patients afflicted with LAS or AIDS."

The specification teaches that it is the presence in a viral extract of the p25 core protein, not the higher molecular weight envelope proteins, that determines whether the extract is recognized immunologically by patient sera. See page 9, lines 8-20:

As a matter of fact and except under exceptional circumstances, sera of diseased patients do not recognize the intact LAV₁ virus. . . . The envelope proteins of the virus appeared as not detectable immunologically by the patients' sera. However as soon as the

core proteins become exposed to said sera, the immunological detection becomes possible. Therefore the invention concerns all extracts of the virus, whether it be the crudest ones – particularly mere virus lyzates [sic] – or the more purified ones, particularly extracts enriched in the p25 protein or even the purified p25 protein.

Discussion

1. The utility rejection

Claims 28-30, 35, and 42 are directed to "immunological complexes" comprising a viral protein and an antibody bound thereto. The examiner rejected these claims under both 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, on the basis that the claimed complexes lack patentable utility. He reasoned that "immune complexes are the end products of the antigen-antibody interaction and it is entirely unclear what utility(ies) reside in the immune complexes themselves." Examiner's Answer, page 4. The examiner argues that the complexes are not useful in immunoassays, because

in immunology, one skilled in the art would routinely use HIV-1 proteins to detect antibodies to HIV-1 or, conversely, use antibodies specific for HIV-1 to detect and/or identify proteins of HIV-1. But one skilled in the art would not use purified immune complexes for such identification. This usage is repugnant to one skilled in the art. Immunological assays do not routinely utilize purified immune complexes in place of purified antibodies or purified antigens for the very basic reason that immune complexes represent the end product of antigen-antibody interactions, not the starting material useful in immunological assays.

Examiner's Answer, page 5.

Appellants argue that the claimed complexes have utility because they are formed during processes for isolating and detecting HIV proteins. Appeal Brief,

pages 10-14. Thus, Appellants argue that the "specification describes the use of immunological complexes, not as mere end products, but as essential parts of immunological methods for the purification and analysis of HIV-1 antigens and antibodies that bind to HIV-1 antigens." <u>Id.</u>, pages 14-15.

"[T]he PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995). The instant specification, however, does not assert a utility for the isolated immune complexes now claimed. The specification asserts that viral extracts containing p25 are useful for detecting HIV-specific antibodies in patient sera. See page 10, line 30 to page 11, line 2, and page 9, lines 15-20. We will assume, for the sake of argument, that that asserted use for the viral proteins would be understood by those skilled in the art to imply the corresponding use of HIV p25-specific antibodies in detecting or purifying p25, although that utility is not expressly asserted.

We also recognize that the immune complexes of the instant claims would be formed in such processes, and specifically in the radioimmunoprecipitation and ELISA assays discussed in the specification (pages 14-19). However, there is an important distinction between products that are formed during a process and products that are useful in a process. Here, the claimed immune complexes are formed during the process of <u>using an antibody</u> to detect or immunopurify a viral protein or during a process of using a viral protein to detect antibody to the

Application No. 08/019,297

protein. The claimed, purified complexes <u>themselves</u>, however, are not useful in carrying out either of these processes.

That is, a person of ordinary skill in the art, starting with a quantity of purified immune complex, cannot use that complex in a diagnostic method, or in a method of purifying HIV protein. Once the complex is formed, as the examiner has pointed out, the only use for it that is disclosed in the specification is in detecting it, either by precipitation or by reaction with a secondary antibody. A product does not have patentable utility merely because its presence can be detected using an appropriate assay. See, e.g., Brenner v. Manson, 383 U.S. 519, 535, 148 USPQ 689, 696 (1966) ("potential role as an object of use-testing" insufficient to show utility under § 101); In re Kirk, 376 F.2d 936, 949, 153 USPQ 48, 55 (CCPA 1967) ("There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher' was recognized, and clearly rejected, by the Supreme Court." (citing Brenner v. Manson)). See also In re Ziegler, 992 F.2d 1197, 1203, 26 USPQ2d 1600, 1605 (Fed. Cir. 1993) (Utility for polymer not established by disclosure that polymer was plastic-like. "[A]t best, Ziegler was on the way to discovering a practical utility for polypropylene at the time of the filing of the German application; but in that application Ziegler had not yet gotten there.").

Once the antibody and viral protein have associated to form the claimed complex, the complex can be used in the disclosed methods of diagnosis or

purification only by first disassociating the antigen and antibody components of the complex. The instant claims, however, are not directed to an isolated antibody or an isolated antigen, the claims are directed to an "immunological complex." The issue, therefore, is whether the specification discloses a patentable utility for an immunological complex <u>as a complex</u>. We agree with the examiner that it does not.

The specification discloses no utility for the claimed immune complexes as complexes. Therefore, we affirm the rejection of claims 28-30, 35, and 42 under 35 U.S.C. § 101 for lack of utility. We also affirm the rejection of these claims under 35 U.S.C. § 112, first paragraph. See Ziegler, 992 F.2d at 1200-01, 26 USPQ2d at 1603 ("If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112.").

2. The enablement rejection

The examiner rejected all of the claims under 35 U.S.C. § 112, first paragraph, on the basis that the specification provides inadequate guidance to enable those skilled in the art to make and use the claimed immune complexes and antibodies to HIV proteins other than p25.² As discussed above, the specification fails to teach how to use the immune complexes of claims 28-30, 35, and 42, and therefore we have affirmed the rejection of these claims under 35 U.S.C. § 112, first paragraph, for lack of enablement. Claims 36 and 45-48

² As noted above, claims 43 and 44 (which are limited to antibodies specific to p25) have been

are directed to antibodies directed against any one of the p15, p25, p36, p42, or p80 proteins of HIV (claims 45-48) and to a method of preparing such antibodies (claim 36).

The examiner rejected these claims as being broader than the enabling scope of the disclosure, noting that the "specification is virtually in its entirety devoted to the identification and isolation of the HIV virus and assays for p25 core protein. . . . The only discussion of antibodies and assays in the specification is directed to p25 protein (see page 21, lines 32-39). No reference is made to the production or utilization of the p15, p36, p42 and p80 antigens of HIV-1." Examiner's Answer, page 6. The examiner also cites Seaver as teaching that only a small percentage of monoclonal antibodies for a given antigen are useful in a diagnostic kit.

The first paragraph of 35 U.S.C. § 112 requires a patent specification to "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." "Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without 'undue experimentation.'" In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991). "Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not

allowed. See the Examiner's Answer, page 3.

Application No. 08/019,297

have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997).

Here, the specification discloses that the p15, p36, p42, and p80 viral proteins recited in the instant claims can be purified from HIV by polyacrylamide gel electrophoresis. See page 8, lines 21-31. The specification also indicates that p36, p42, and p80 "may represent the major envelope proteins." <u>Id.</u>, lines 28-31. Finally, the specification contains the following guidance relating to antip25 antibodies:

The invention finally also relates to the biological reagents that can be formed by the LAV extracts containing the p25 protein or by the purified p25 protein, particularly for the production of antibodies directed against p25 in animals or of monoclonal antibodies.

Page 21, lines 32-37. However, the specification does not disclose how to make antibodies to any of these proteins.

Appellants argue that the specification discloses how to make immune complexes and that those of skill in the art would recognize that such immune complexes could simply be dissociated in order to make the purified antibodies of the instant claims. Appeal Brief, page 21. Alternatively, Appellants argue, those of skill in the art would have known how to make the claimed antibodies from the viral extracts or PAGE-purified proteins disclosed in the specification. Appeal Brief, pages 22-23. Finally, Appellants argue that they have provided "objective evidence of enablement," in the form of six exhibits attached to the amendment

filed March 9, 1999 (Paper No. 40), which show that "the claimed antibodies could be purified following the teachings of the specification and conventional techniques without undue experimentation." Appeal Brief, page 22.

These arguments are not persuasive. The specification's only mention of HIV proteins other than p25 is found on pages 8-9. The relevant passages disclose the proteins p15, p36, p42, and p80 as being putative viral proteins detectable by denaturing gel electrophoresis (page 8, lines 21-31) and also disclose that the putative envelope proteins (p36, p42, and p80) are "not detectable immunologically by the patients' sera" (page 9, lines 11-13).

Where, as here, a specification provides only what amounts to a passing reference to a later-claimed invention, the specification's deficiencies cannot be rectified by asserting that all the disclosure required to enable the invention is within the skill of the art. "[A] specification need not disclose what is well known in the art. However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. . . . It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." Genentech v. Novo Nordisk, 108 F.3d at 1366, 42 USPQ2d at 1005 (citation omitted).

Even assuming, for the sake of argument, that those of skill in the art would have been able to make the claimed antibodies without undue

experimentation, the specification still fails to enable the instant claims, because it fails to adequately teach how to use the claimed antibodies. The specification states that <u>p25</u>-specific antibodies "are liable of forming useful tools in the further study of antigenic determinants of LAV viruses," page 21, lines 37-39, but it provides no guidance whatever on how to use antibodies specific to p15, p36, p42, or p80. The specification admits to some doubt as to whether p15 is even a viral protein. See page 8, lines 21-24 ("The viral origin of other proteins seen in polyacrylamide gel electrophoresis of purified virus is more difficult to assess. A p15 protein could be seen after silver staining, but was much weaker after ³⁵S-methionine."). The specification also discloses that the envelope proteins are not useful in diagnosis. See page 9, lines 11-15 ("The envelope proteins of the virus appeared as not detectable immunologically by the patients' sera. However as soon as the core proteins become exposed to said sera, the immunological detection becomes possible.").

Nowhere does the specification disclose using an antibody that binds an HIV protein other than p25 for diagnosing AIDS or for anything else. For example, the specification states at page 10, line 30 to page 11, line 2, that the invention relates to a method of diagnosing AIDS comprising contacting patient serum with "a virus extract as above defined." In view of the previous disclosure that patient serum does not contain antibodies to the envelope proteins p36, p42, and p80, this disclosure would reasonably be understood to refer to extracts containing viral p25 protein.

The specification also states that the invention "relates to the biological reagents that can be formed by the LAV extracts containing the p25 protein or by the purified p25 protein, particularly for the production of antibodies directed against p25 in animals or of monoclonal antibodies. These antibodies are liable of forming useful tools in the further study of antigenic determinants of LAV viruses or LAV-related viruses." Page 21, lines 32-39. No similar disclosure is made with respect to other HIV proteins such as p15, p36, p42, or p80. Nor does the specification disclose how to use HIV proteins in methods other than in diagnosis of AIDS or how to use HIV-specific antibodies in methods other than the "study of antigenic determinants of LAV viruses."

The closest the specification comes to disclosing a method of using p15, p36, p42, and p80, or antibodies thereto, is in its references to viral extracts. See, e.g., page 9, lines 15-19 ("[T]he invention concerns all extracts of the virus, whether it be the crudest ones – particularly mere virus lyzates [sic] – or the more purified ones, particularly extracts enriched in the p25 protein or even the purified p25 protein."). When these references to viral extracts are read in the context of the specification as a whole, however, it is clear that the critical component in the extracts is p25. In any event, the specification's vague references to crude viral extracts is not the "full, clear, concise, and exact" disclosure that is required by the statute. See Genentech v. Novo Nordisk, 108 F.3d at 1366, 42 USPQ2d at 1005 ("Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been

carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention."). "[T]he law requires that the disclosure in the application shall inform them how to use, not how to find out how to use for themselves." In re Gardner, 427 F.2d 786, 789, 166 USPQ 138, 141 (CCPA 1970).

Appellants argue that

Following the teachings of the specification, the skilled artisan could also use these antibodies to bind a labeled secondary antibody. . . . Consequently, the skilled artisan needs no undue experimentation to make and use the antibodies.

Appeal Brief, page 21.

This argument is not persuasive. The claimed antibodies are "directed against an antigen . . .selected from p25, p15, p36, p42, and p80." See claim 45. Thus, the claimed antibodies do not "bind a labeled secondary antibody," as Appellants assert; rather, they bind one of the specified HIV proteins.³ The specification discloses no method for using the instantly claimed antibodies, directed against p15, p36, p42, or p80, and therefore fails to teach those skilled in the art how to use the claimed invention.

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³ The claimed antibodies might be <u>bound by</u> a labeled secondary antibody, but at best that would be relevant to teaching how to use the labeled secondary antibody. In any case, since the specification teaches that the HIV envelope proteins are not useful diagnostically (page 9, lines 11-13), the specification provides no context in which a skilled artisan would use an immunoassay for detecting the instantly claimed antibodies.

3. The written description rejection

The examiner also rejected all of the claims under 35 U.S.C. § 112, first paragraph, as being unsupported by an adequate written description. He explained that

[t]here is no evidence in the specification other than the one paragraph at page 21 to provide support for the claimed invention. All of Appellant's [sic] teachings are directed to making and using the viral proteins, not antibodies or immune complexes. . . . Appellant's [sic] only written description is a short paragraph briefly contemplating antibodies to p25 (see specification, page 21, last paragraph). There is no indication that Appellant[s] contemplated antibodies to other proteins, how to make and use immune complexes, antibodies labeled with a detectable label, or specific methods of making antibodies."

Examiner's Answer, page 8. The examiner concluded that the subject matter of the instant claims "was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Id.

"In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide <u>in haec verba</u> support for the claimed subject matter at issue." <u>Purdue Pharma L.P. v. Faulding, Inc.</u>, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000). Nonetheless, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. <u>See id.</u> "Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims." <u>Id.</u>

Claims 30 and 42 are limited to immune complexes comprising HIV p25 protein and an antibody against p25. The specification discloses that, "[i]n order to determine which viral antigen was recognized by antibodies present in the patient's sera, several immunoprecipitation experiments were carried out." Page 7, lines 20-22. These experiments showed that a "p25 protein present in the virus-infected cells from patient 1 and LC1 cells infected with this virus was specifically recognized by serum from patient 1." Id., page 8, lines 2-5. That is, the viral p25 protein was recognized (bound) by antibodies in the serum of HIV-infected patient 1. As Appellants argue, this disclosure is sufficient to convey that those skilled in the art were in possession of immune complexes comprising the p25 protein of HIV and an antibody against that protein. We therefore reverse the rejection of claims 30 and 42 on the basis of inadequate written description.

The rest of the claims subject to this rejection read on antibodies against HIV proteins other than p25 (including p15, p36, p42, and p80), or immune complexes comprising such antibodies. As discussed above, the HIV proteins other than p25 recited in the instant claims are discussed by the specification only in passing. The specification indicates that, at the time the instant application was filed, Appellants were unsure even whether the other proteins were derived from HIV. See the specification, page 8, lines 21-31:

The viral origin of other proteins seen in polyacrylamide gel electrophoresis of purified virus is more difficult to assess. A p15 protein could be seen after silver staining. . . . In the higher MW range, a contamination of the virus by cellular proteins, either inside

or outside the viral envelope, is likely. A 36K and a 42K protein and a 80K protein were constantly found to be associated with the purified virus and may represent the major envelope proteins.

The specification also indicates that the putative envelope proteins (p36, p42, and p80) were not immunologically reactive with patient sera. See page 9, lines 11-15: "The envelope proteins of the virus appeared as not detectable immunologically by the patients' sera. However as soon as the core proteins become exposed to said sera, the immunological detection becomes possible."

The specification does not indicate that antibodies to these proteins had been raised at the time the instant application was filed, nor does it suggest that such antibodies should be raised or that such antibodies would be useful in AIDS diagnosis if they were raised. At best, the specification indicates that Appellants were in possession of crude virus lysates that were useful for AIDS diagnosis but which contained p25 in addition to other viral proteins.

Thus, we agree with the examiner that the instant specification does not reasonably convey to those skilled in the art that Appellants were in possession, at the time the application was filed, of the completed inventions of the instant claims—antibodies specific to HIV proteins other than p25, immune complexes comprising such antibodies, or methods of making such antibodies. Put another way, we agree with the examiner that one skilled in the art, reading the original disclosure, would not immediately discern from the disclosure the limitations at issue in the claims. See Purdue Pharma, 230 F.3d at 1323, 56 USPQ2d at 1483.

Appellants argue that the specification's disclosure of PAGE-purified viral proteins, combined with the specification's statement that "the invention concerns all extracts of the virus, whether it be the crudest ones . . . or the more purified ones," would have led those skilled in the art to conclude that Appellants contemplated using the PAGE-purified proteins as "more purified" extracts to make the claimed antibodies and immune complexes. See the Appeal Brief, pages 29-30.

This argument is not persuasive. The only HIV-specific antibodies mentioned in the instant specification are those directed against p25. See page 21, lines 32-37. The specification discloses that sera from HIV-infected patients does not contain antibodies to p36, p42, or p80. See page 8, lines 28-31 (p36, p42, and p80 "may represent the major envelope proteins") and page 9, lines 11-13 ("The envelope proteins of the virus appeared as not detectable immunologically by the patients' sera."). The specification does not describe procedures for making or purifying antibodies to HIV proteins, nor does the specification describe immune complexes comprising antibodies directed to HIV proteins other than p25. See page 8, lines 2-5 ("A p25 protein present in the virus-infected cells from patient 1 and LC1 cells infected with this virus was specifically recognized by serum from patient 1." (emphasis added)).

Thus, the specification does not convey with reasonable clarity to those of skill in the art that Appellants were in possession of the antibodies and immune complexes now claimed, as of the filing date of the instant application. One

skilled in the art, reading the original disclosure, would not immediately discern the limitations at issue in the claims. See Purdue Pharma, 230 F.3d at 1323, 56 USPQ2d at 1483.

Appellants also argue that

The extract used of the ELISA was a crude extract of purified HIV-1 virus. As Appellants had demonstrated, purified HIV-1 virus contained p25, p15, p36, p42, and p80. Accordingly, when Appellants purified the immunological complexes formed with the crude extract of purified HIV-1 virus, they were purifying all the immunological complexes formed between the proteins in this extract and the patient sera. The skilled artisan recognizes that this would include immunological complexes containing p25, p15, p36, p42, and p80 proteins and antibodies against these proteins. Consequently, the skilled artisan would conclude that Appellants had possession of purified immunological complexes formed between p25, p15, p36, p42, and p80 and patient sera.

Appeal Brief, pages 31-32.

This argument is specious. The record contains no evidence to support Appellants' contention that the patient sera used to form immune complexes with HIV extract contained antibodies to any of p15, p36, p42, or p80. The evidence of record, in fact, shows just the opposite. The specification discloses that sera from HIV-infected patients does not contain antibodies to any of p36, p42, or p80. See page 9, lines 11-13: "The envelope proteins of the virus appeared as not detectable immunologically by the patients' sera."

The evidence in the record would not have led the skilled artisan conclude that Appellants were in possession of antibodies to HIV proteins other than p25, or immune complexes comprising such proteins, at the time the application was

filed. The rejection of claims 28, 29, 35, 36, and 45-48 for lack of adequate written description is affirmed.

4. The anticipation rejection

The examiner rejected all of the claims under 35 U.S.C. § 102(b) as being anticipated by Di Marzo Veronese. The examiner characterizes Di Marzo Veronese as "disclos[ing] monoclonal antibodies to the major core protein of HTLV-III. This antigen is the same antigen as Appellant's [sic] designated p25 of LAV." Examiner's Answer, page 9.

Appellants do not dispute that the products and methods disclosed by Di Marzo Veronese meet the limitations of the instant claims. Appellants argue, however, that the reference is not prior art, because the instant application is entitled to priority under 35 U.S.C. § 120 to a chain of prior applications reaching back to December 5, 1983. The examiner denied Appellants the benefit of priority under § 120 on the basis that the previously filed applications did not provide an enabling disclosure or adequate written description of the instant claims.

"It is elementary patent law that a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112." In re Chu, 66 F.3d 292, 297, 36 USPQ2d 1089, 1093 (Fed. Cir. 1995).

Appellants acknowledge that the priority applications are identical or nearly identical to the instant specification. See Paper No. 2, filed February 18, 1993, page 2 (amending the specification to insert "This application is a division of application Serial No. 07/876,297, . . . which is a continuation of application Serial No. 07/117,937, . . . which is a continuation of application Serial No. 06/785,638, . . . which is a continuation of application Serial No. 06/558,109, filed December 5, 1983."); Appeal Brief, page 42 ("Appellants claim priority to British application GB 83/24800, filed September 15, 1983. The disclosure of GB 83/24800 is nearly identical to the instant specification.").

We have concluded that none of the rejected claims finds both an enabling disclosure and an adequate written description in the instant specification. Since Appellants have pointed to no disclosures in the earlier-filed applications that are not also in the instant application, our conclusion that the instant specification does not enable or adequately describe the instant claims applies equally to the identical or nearly identical parent applications. The instant claims are therefore not entitled to priority under 35 U.S.C. §§ 119 or 120, and Di Marzo Veronese is prior art under 35 U.S.C. § 102(b).

Since Appellants do not dispute that Di Marzo Veronese identically discloses the products and methods of the instant claims, and since Di Marzo Veronese is prior art under § 102(b), we affirm the rejection for anticipation.

Summary

We affirm the rejection of claims 28-30, 35, and 42 because the specification does not disclose a patentable utility for the claimed immune complexes. With the exception of the written description rejection of claims 30 and 42, we affirm the rejection of all the claims under 35 U.S.C. § 112, first paragraph, because the specification provides neither an enabling disclosure nor an adequate written description of the claimed invention. Finally, we affirm the rejection for anticipation because the none of the claims on appeal are entitled to priority under either 35 U.S.C. §§ 119 or 120, and therefore Di Marzo Veronese is prior art under 35 U.S.C. § 102(b). Thus, we affirm the rejection of all the claims on at least one ground.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

<u>AFFIRMED</u>

SHERMAN D. WINTERS Administrative Patent Judge)))
DONALD E. ADAMS Administrative Patent Judge)) BOARD OF PATENT
)) APPEALS AND
) INTERFERENCES
ERIC GRIMES Administrative Patent Judge))

Appeal No. 2000-1929 Application No. 08/019,297

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